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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,892	10/29/2003	Christophe Boulle	016800-545	4119

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EXAMINER	
YOUNG, SHAWQUIA	
ART UNIT	**PAPER NUMBER**
1626	

NOTIFICATION DATE	DELIVERY MODE
09/17/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/694,892	BOULLE ET AL.	
	Examiner	Art Unit	
	Shawquia Young	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *25-47,51 and 52* is/are withdrawn from consideration.

5)☒ Claim(s) *1-3,7-10 and 48-50* is/are allowed.

6)☒ Claim(s) *4-6 and 11-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-52 are currently pending in the instant application.

I. Response to Amendment and Arguments

Applicants amendments to the claims and remarks filed on July 5, 2007 have been entered in the application and considered.

Applicants' amendments and arguments have overcome the following rejections and objections:

The 35 USC 112, first paragraph rejection of claims 3, 5, 6, 8 and 10-24 as failing to comply with the written description rejection.

The 35 USC 112, second paragraph rejection of claims 1-24 and 48-50 as being indefinite.

The objection of the Oath or Declaration because the title of the invention is not in the English language.

However, upon further examination of the current amendments to the claims, a new ground(s) of rejection is made in view of claims 4-6 and 11-24 under 35 USC 112, 1st paragraph, enablement.

II. Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-6 and 11-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inducing and/or stimulating the growth of keratin fibers, and/or reducing their loss and/or increasing their density does not reasonably provide enablement for a method of inhibiting 15-hydroxyprostaglandin dehydrogenase or an intended treatment of disorders associated with 15-hydroxyprostaglandin dehydrogenase. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue".

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,

2. the state of the prior art,

3. the predictability or lack thereof in the art,

4. the amount of direction or guidance present,

5. the presence or absence of working examples,

6. the breadth of the claims,

7. the quantity of experimentation needed, and

8. the level of the skill in the art.

In the instant case,

The nature of the invention

The nature of the invention of is a method of inhibiting 15-hydroxyprostaglandin dehydrogenase and a method for the manufacture of a care or treatment composition for human keratin fibers, which intended to treat disorders associated with 15-hydroxyprostaglandin dehydrogenase. Applicants fail to list diseases or disorders that are encompassed by the above methods in the claims. Therefore Applicants claims encompass disease or disorders that are known to be associated with inhibition of 15-hydroxyprostaglandin dehydrogenase as well as diseases that have not been discovered that are associated with the inhibition of 15-hydroxyprostaglandin dehydrogense.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that the pharmacological art involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease by what mechanism). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic

regimen on its face.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art, for example diseases or disorders associated with 15-hydroxyprostaglandin dehydrogenase, is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to therapeutic effects of any condition considered a tetracycline compound responsive state, whether or not the condition is effected by the activity of the products of the claimed invention would make a difference.

Applicants claims are drawn to a method of inhibiting 15-hydroxyprostaglandin dehydrogenase. It has been suggested by Wolf, et al. that 15-hydroxyprostaglandin dehydrogenase plays a role in tumor suppression of breast cancer.

Applicants' claims also include the treatment of breast cancer. The state of the prior art is that cancer therapy remains highly unpredictable. Breast cancer is a cancer that starts in the tissues of the breast. There are two main types of breast cancer: ductal carcinoma and lobular carcinoma. Treatment of breast cancer is based on my factors, including type and stage of the cancer, whether the cancer is sensitive to certain hormones and whether or not the cancer overproduces a gene called HER2/neu. In general cancer treatment may include chemotherapy, radiation therapy,

surgery, hormonal therapy and targeted therapy. Most women receive a combination of treatments. For women with stage I, II or III breast cancer, the main goal is to treat the cancer and prevent it from returning. For women with stage IV cancer, the goal is to improve symptoms and help them live longer. Breast cancer is a complex disease and can be difficult to treat depending on how advanced the cancer is and if the cancer has spread to other parts of the body.

((<URL:http://www.nlm.nig.gov/medlineplus/ency/article/000913.htm>).

It is known, in general, that the challenge of cancer treatment has been to target specific therapies to pathogenetically distinct tumor types, that cancer classification has been based primarily on morphological appearance of the tumor and that tumors with similar histopathological appearance can follow significantly different clinical courses and show different responses to therapy (Golub et al. page 531). Furthermore, it is known that chemotherapy is most effective against tumors with rapidly dividing cells and that cells of solid tumors divide relatively slowly and chemotherapy is often less effective against them. This example shows the unpredictability in the art and the different treatment protocols.

The amount of direction present and the presence or absence of working examples

The only direction or guidance present in the instant specification is minimal. The specification only gives a limited list of conditions considered as being related to15-hydroxyprostaglandin dehydrogenase. There are no working examples present for the

treatment of any specific disease or disorder.

Test assays and procedure are provided in the specification at pages 46-50 for demonstration of 15-PGDH-specific inhibitory properties. It is inconceivable as to how the claimed compounds can treat the various diseases, both known and unknown, embraced by the instant claims.

Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use of the instant compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

The breadth of the claims

The breadth of the claims is a method of inhibiting 15-hydroxyprostaglandin dehydrogenase and a method for the manufacture of a care or treatment composition for human keratin fibers, which intended to treat disorders associated with 15-hydroxyprostaglandin dehydrogenase.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what diseases would be benefited by the activity of the claimed styrylpyrazole compounds and would furthermore then have to determine which of the claimed compounds in the instant invention would provide treatment of the

diseases.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* or *in vivo* screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

The specification fails to provide sufficient support of the broad use of the claimed compounds of the invention for a a method of inhibiting 15-hydroxyprostaglandin dehydrogenase and a method for the manufacture of a care or treatment composition for human keratin fibers, which intended to treat disorders associated with 15-hydroxyprostaglandin dehydrogenase. . As a result necessitating one of skill to perform an exhaustive search for which diseases can be treated by what compounds of the invention in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated by the

compound encompassed in the instant claims, with no assurance of success.

This rejection can be overcome, for example, by deleting the method claims.

III. Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 6:30 AM-3:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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